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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,296

12/22/2005

Peter William Gage

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EXAMINER

CHANDRAKUMAR, NIZAL S

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

01/05/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,296	Applicant(s) GAGE ET AL.	
	Examiner NIZAL S. CHANDRAKUMAR	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-169 is/are pending in the application.
- 4a) Of the above claim(s) 4-160 and 164-168 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 161-163 and 169 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/12/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-3, 161-163 and 169 in the reply filed on 11/26/2010 is acknowledged. The traversal is on the ground(s) that there would not be serious burden if all the groups are examined together. This is not found persuasive because of the reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-160, 164-168 withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions, there being no allowable generic or linking claims. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/26/2010.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

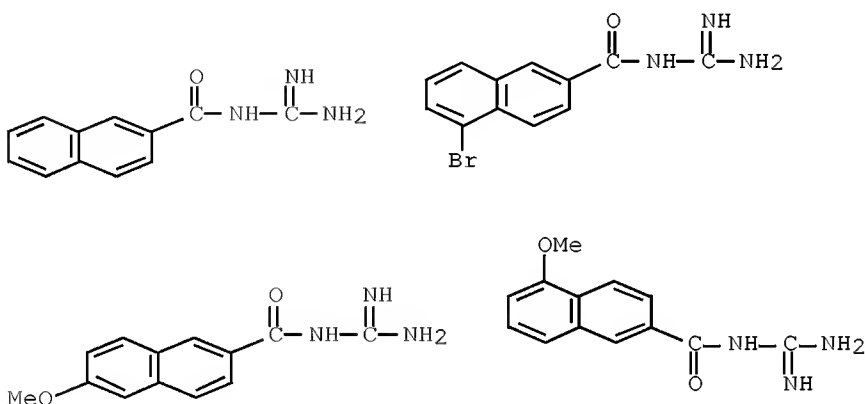
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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

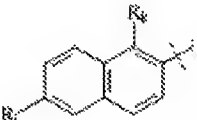
Claims 1-3, 161-163 and 169 are rejected under 35 U.S.C. 103(a) as obvious over

Yamamoto et al. Chemical & Pharmaceutical Bulletin (1997), 45(8), 1282-1286.

Yamamoto et al. teach



The first compound shown above was originally claimed by the applicant and deleted later from the instantly filed claims to overcome anticipatory rejection, corresponds to compound of formula of claim 1 (and dependent claims 2 and 3)

wherein R1 = , Rk and Rj are H.

(Deleted from claim 161 second page, line 14, 1-naphthoylguanidine).

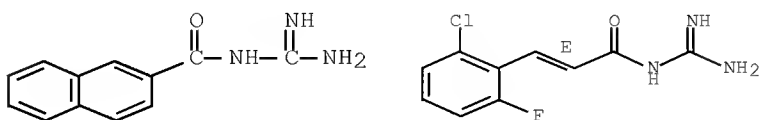
Thus Yamamoto et al. teach close analogs of the compounds of the instant claims. Yamamoto et al teach that commonly used substituents or their position of

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attachment to guanidine moiety are not deleterious to the pharmaceutical properties of acylguanidines. Positional analogs and adjacent homologs are obvious variants and it would be obvious to one skilled in the art to make additional acylguanidines to arrive at compounds within the scope of the Applicant's claims, because structurally similar compounds are anticipated to possess similar properties.

Claims 1-3, 161-163 and 169 rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. Chemical & Pharmaceutical Bulletin (1997), 45(8), 1282-1286 and further in view of Bream, Arzneimittel-Forschung (1975), 25(10), 1477-82.

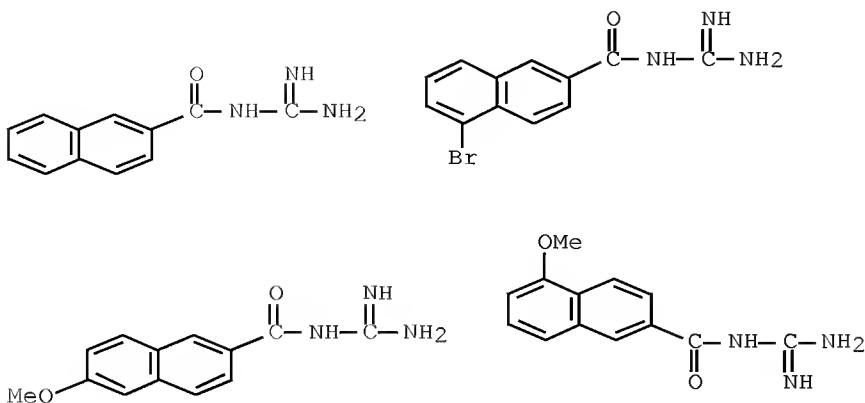
Instant claims are drawn to acylguanidines wherein the acyl part is varied with large number of groups. Examples of compounds of instant claims 1 and 161. .



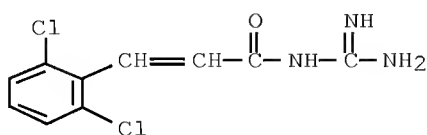
Yamamoto et al. teach

Yamamoto et al. teach

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Bream teaches



Yamamoto et al. and Bream do not teach all the compounds of the instant claims.

However, it would have been obvious to one of skill in the art would make applicants compounds with reasonable expectation of success because the cited prior arts teach that the pharmaceutical use of acylguanidines is not adversely affected by the substituents on the acyl part.

The difference between the prior art compounds and the instantly claimed compounds are substituents and positional isomerism commonly used in the medicinal chemistry art for optimizing biological properties. As such one of skilled in the art would modify the prior art acyl guanidines to arrive at the instantly claim limitations with reasonable expectation of success because Yamamoto et al. and Bream teach different acyl groups in acyl guanidine basic pharmacophore provided opportunity for medicinal chemistry

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effort to arrive at compounds with improved pharmaceutical properties. Obviousness based on similarity of structure and functions entails motivation to make the claimed compound in expectation that compounds of similar in structure will have similar properties; therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new compounds.

Prior art not relied upon: Acyl guanidines are well known compounds, See US 7041702, US 6011059, US 5733934, US 5719169, US 5567734, US 4496573.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nizal S Chandrakumar/
Examiner, Art Unit 1625